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Clinical Report 2014

Open House Medical Centre

English

TABLE OF CONTENTS

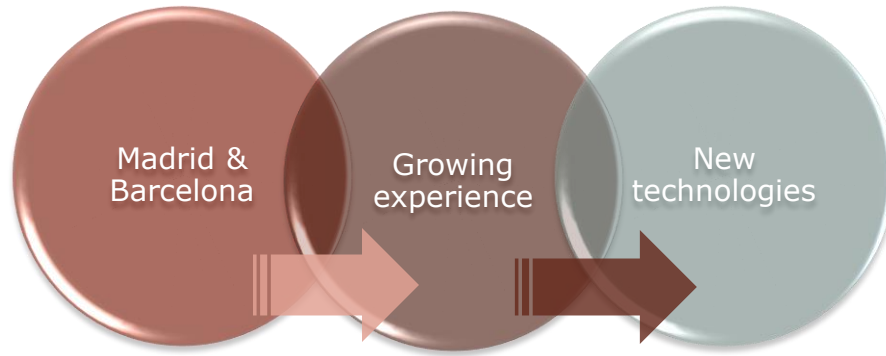
Overview by our clinical responsible person

Section 1: Clinical remit

- Patients seen (by sexuality, race, age and language)
- New technologies
- Orientation from our website
- Institutional relations and inspections
- Complaints and legal action
- Internal quality control

Section 2: Consultations and pathologies

- Testing for sexual contact alone without symptoms
- Clinical psychology sessions
- Syphilis
- Gonorrhoea
- Chlamydia
- HIV
- Non-specific urethritis and prostatitis
- Antibacterial post exposure prophylaxis
- Moluscum contagiosum
- Cases of note
- Other pathologies
- Research
- Contact and queries



Summary by our clinical responsible person

2014 has been a year of significant changes in Open House. Our new clinic in Barcelona has allowed us to have a true nationwide dimension for our customers, and with a catalan version of our webiste on the horizon, we hope to be able to offer a high quality information service in three languages, covering aspects such as sexually transmitted infections, the risks thereof and the correct/relevant tests.

Open House has acquired new technology that allows more precision in the diagnosis of chlamydia and gonorrhoea (nucleic acid amplification tests, or PCR). In the case of these genital infections we will be able to increase detected cases by 7% for chlamydia and 1% for gonorrhoea, with overall detection levels reaching figures around 99.9%. Additionally we are now the only private clinic in Spain that can perform these test in just 90 minutes. Since European Guidelines now recommend this PCR test as the test of choice for detecting gonorrhoea and chlamydia in the throat or rectum, rather than the less precise cultures, we have seen an important increase in detection rates.

Open House will be offering new technologies and novel services in the near future so we can remain a high quality clinical service provider for our customers.

Our clinical experience continues to grow, now with four doctors able to share their cases and experiences. We are also consolidating our knowledge in Clinical Standard Operating Procedures which govern how we investigate diseases and chose treatment options. The quality of our clinical work is taken seriously at Open House.

This year we have performed consultations for **3552** people in our clinics, with around some **5900** tests for sexually transmitted infections being performed and a total of **672** positive cases being treated. Our success rate in treating infections continues to increase and is well above figures seen in other centres.



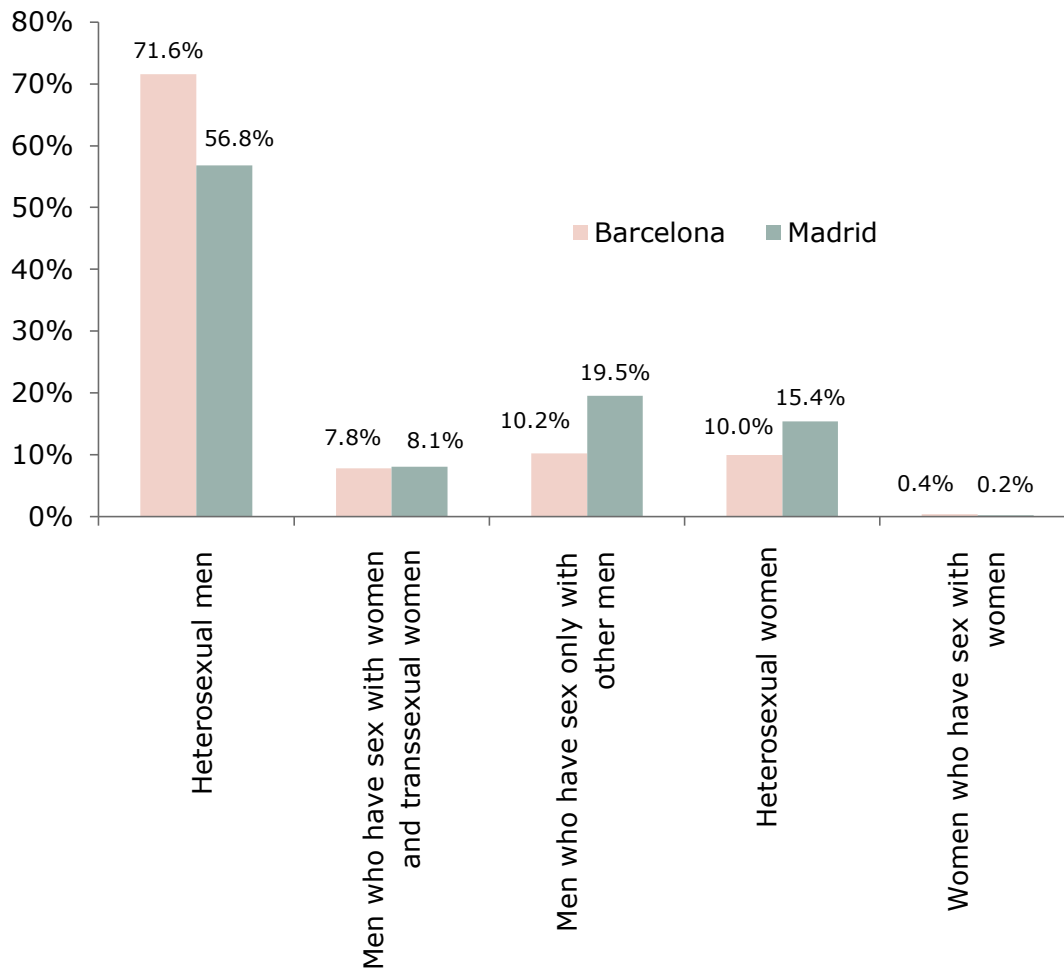
Dr. Stephen Chapman
Medical director

SECTION 1: CLINICAL REMIT

PATIENTS SEEN

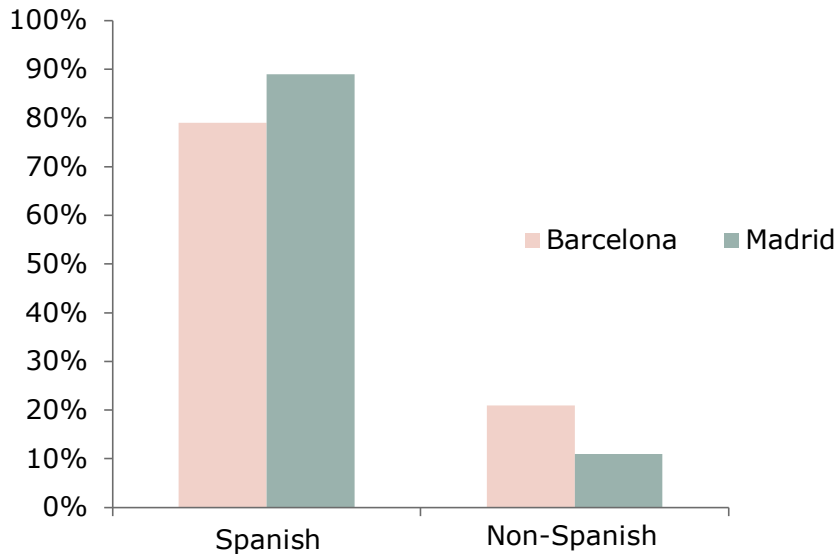
(a) Classified by sexually:

Graph 1: breakdown of patients seen in both clinics in 2014 by sexuality

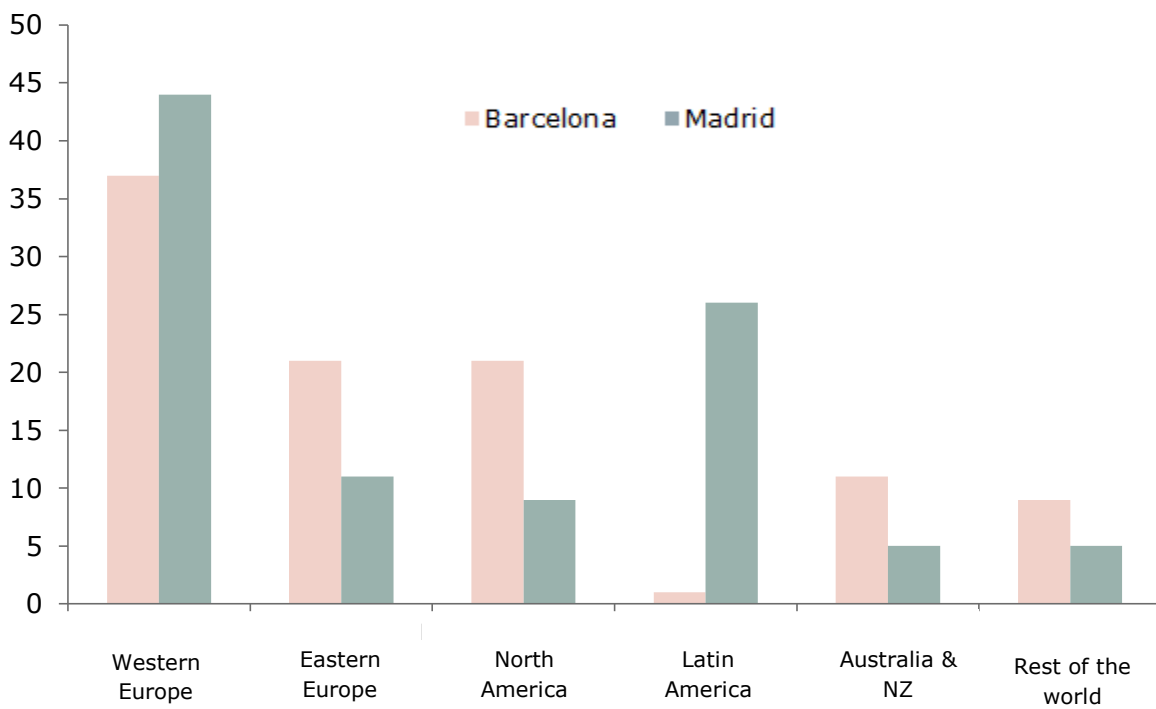


(b) Classified by nationality:

Graph 2: breakdown of patients seen in both clinics in 2014 by nationality

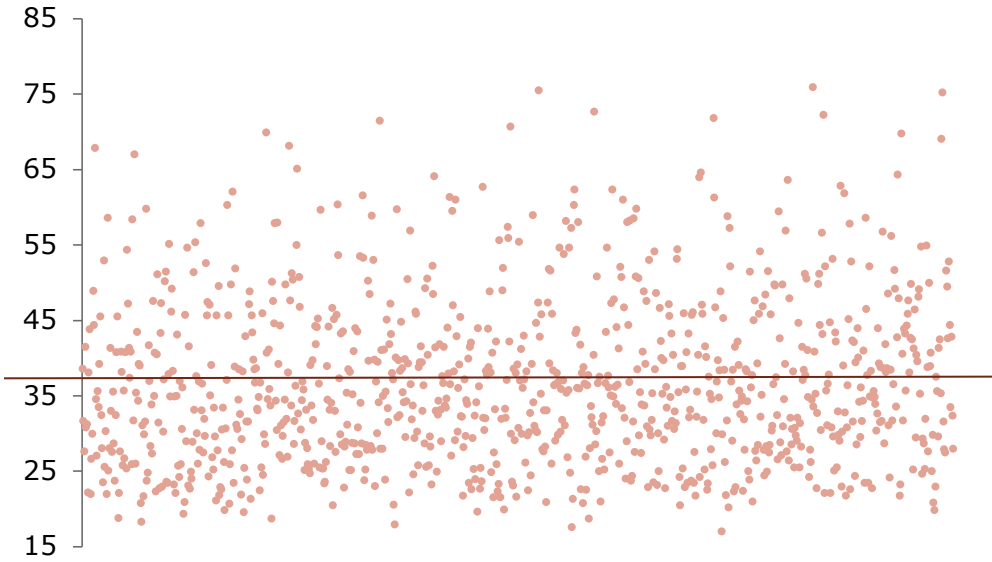


Graph 3: breakdown of non-Spanish patients seen in both clinics in 2014 (%) by region

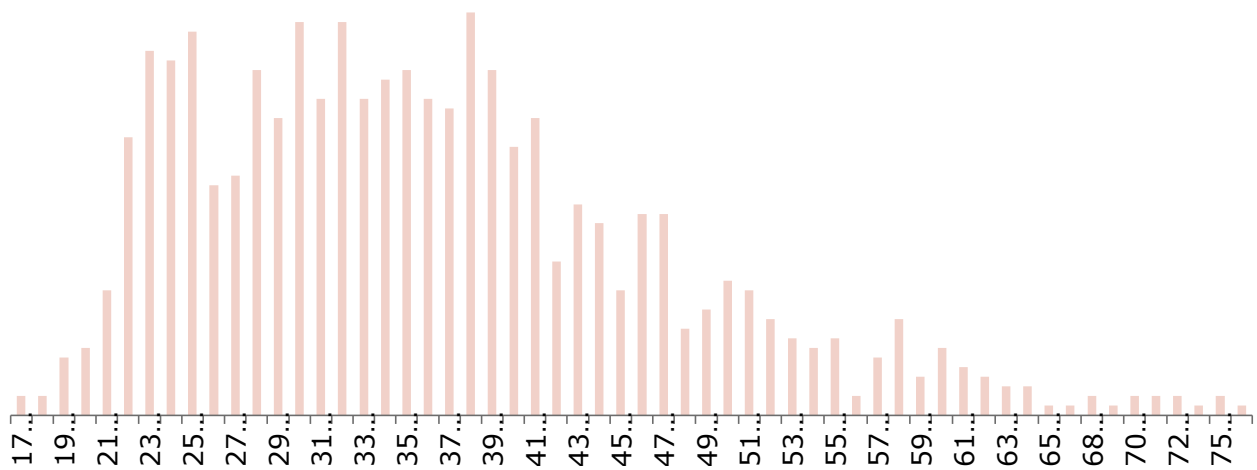


(c) Breakdown by age:

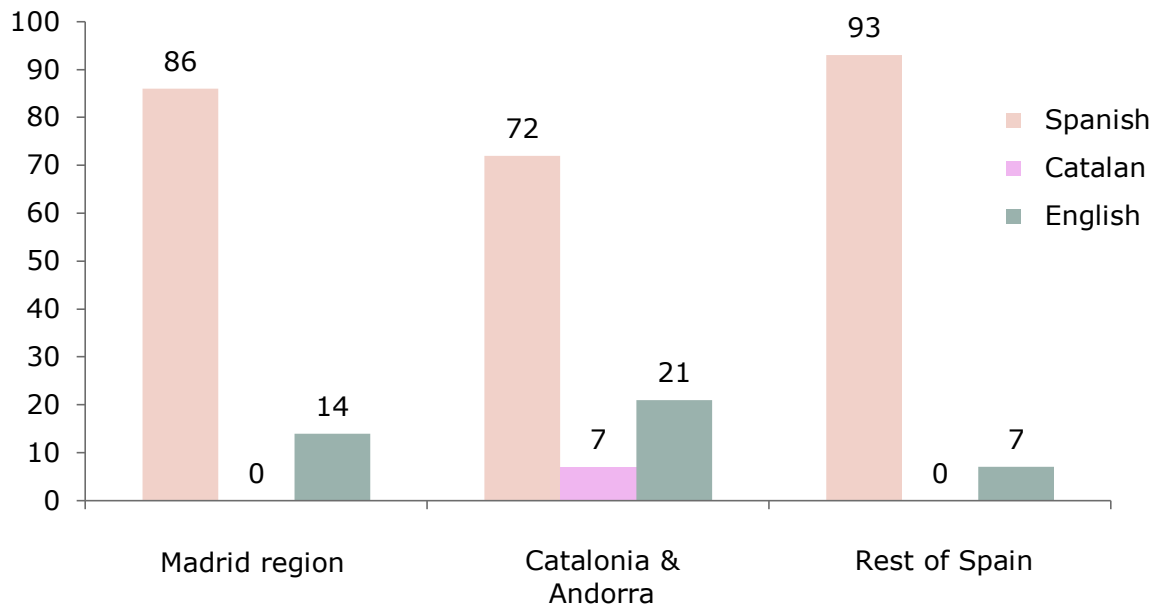
Graph 4: age (years) of each patient (Barcelona) throughout 2014 - median age 37 years



Graph 5: relative age distribution (years) of new patients in both clinics 2014:



Graph 6: Language of choice in searches and browsing of the website www.openhouse.es contents throughout 2014 (%) according to data from Google®:



NEW TECHNOLOGIES

High-sensitive gonorrhoea and chlamydia testing:

This year, open House has acquired new technology that allows more precise detection of gonorrhoea and chlamydia (nucleic acid amplification tests, or PCR). This technique searches for DNA specific to *Neisseria gonorrhoeae* and *Chlamydia trachomatis* and if detected makes millions of copies giving a stronger positive signal. For this reason it is vastly superior in detection compared to other techniques.



We have always been able to offer this test before now, but with a turn-around-time for results of between 4 to 7 days. But this new technology makes us the only private clinic in Spain that can do these

tests in just 90 minutes.

And the advantages? In the case of these two infections in the genitals, we can now diagnose 7% more cases of chlamydia and 1% more cases of gonorrhoea compared to the rapid tests we use, with detection rates as high as 99.9% of all cases.

Now that European guidelines for the detection of gonorrhoea and chlamydia in the throat and rectum recommend this PCR technique because they are much more sensitive than doing standard culture tests (detection limited to about 90% of cases), we have seen a significant increase in positive results in the throat and rectum, including, of course, asymptomatic cases. We are therefore now able to eradicate the infection so that it does not pose a risk to our patient's other sexual contacts.

Some of the nucleic acid amplification techniques on the market today have been shown to have a problem of cross reactions between bacteria in the Chlamydia and Neisseria families (Neisseria is the family to which gonorrhoea belongs) but our technology only registers DNA which is specific to the individual species and therefore eliminates this risk.

To date we have performed more than 1000 tests with this technique which is slowly overtaking the use of our rapid tests.

ORIENTATION FROM OUR WEBSITE

Our website has a great deal of useful information supported by scientific publications from medical journals. It is not just simply our medical team's "opinions or beliefs".

Our medical director also provides an email service for doubts that arise from reading our website (elequipo@openhouse.es)

Emails answered in 2014: **1977**

Although we are not able to give a comprehensive clinical evaluation by email, we have helped many people in Spain and in other countries with queries they have about sexually transmitted infections. At the beginning of 2015 we shall be launching a new mobile-friendly version of the website.



New clinical recommendations as set out by Spanish, European and international health authorities regarding the use of VIH, hepatitis, syphilis, gonorrhoea and chlamydia tests will be incorporated into this new version in 2015.

INSTITUTIONAL RELATIONS & INSPECTIONS

There has been no inspection by health authorities of either clinic this year. Open House therefore remains a health centre that has only ever been inspected as part of the standard 5 yearly checkup and has always passed these inspections without any significant findings.

Open House Barcelona has started to have more dialogue in complex cases with the public STI centre in Barcelona called CAP Drassanes. Similarly all cases of suspected antibiotic resistance in gonorrhoea have been sent to them for appraisal.

COMPLAINTS & LEGAL ACTION

Official complaints forms have been used twice in Open House during 2014.

In both cases this was a client who was extremely nervous about the possibility of having an ITS, arrived late for their appointment and had to wait 30 more minutes as a result. This information as presented to the regional health authority who decided no further action or inspection was required.

There have been no professional complaints or legal proceedings against the clinic.

The medical notes that the four doctors in Open House make have undergone internal audit for quality and precision, and any possible improvements have been fed back to the medical team.

INTERNAL QUALITY CONTROL – CHANGES SINCE THE 2014 ANNUAL REVIEW

Each year Open House performs a review of all medical literature published in our field in order to adapt our practice to new recommendation and clinical guidelines. The changes are christalised in our Standard Operating Procedures (SOPs), the “laws” which govern our clinical and working practices. As result of our literature review this year we have updated the following SOPs.

Non-clinical SOPs:

- 03. Sample collection and processing
- 06. Telephone contacts
- 07. Reception and processing of patients
- 10. Autonomous Community dossier maintenance
- 11. Application of Data Protection laws

Clinical SOPs:

- 50. Basic clinical history, physical examination and simple collection
- 4. Urethritis and prostatitis
- 56. Anorectal pathology
- 58. HIV testing
- 60. Antibacterial post exposure prophylaxis

- 72. Gonorrhoea (pharyngeal, cervical, rectal, urethral and complicated cases)
- 80. ITS in men who have sex with men
- 81. ITS in men with HIV

One important change that we brought into effect in December of 2014 was to do with the antibody and p24 antigen test for HIV.

This test is a useful tool in the detection of early HIV infections, but the manufacturer has changed their recommendations regarding its use, being backed up by the Spanish Agency for Medications and Health Products.

The new recommendation states that a negative result with this test should be backed up by a further antibody test at three months. They decided to adopt these measures because there has been a case of a patient with a subtype of HIV that we do not usually see in Europe who had a negative p24 antigen test during his seroconversion. Basing their argument on this case the company felt it could be prudent to recommend this double checking, and Open House, as always, will adapt itself to these guidelines.

SECTION 2: CONSULTATIONS & PATHOLOGIES

MEDICAL CONSULTATIONS & TESTS PERFORMED

This year we have performed 3552 medical consultations. 672 ITSs have been diagnosed. We have referred cases on for specialist help in only 1.2% of all cases.

TESTING FOLLOWING SEXUAL CONTACT WITHOUT SYMPTOMS

Medical consultations this year in which we went on to perform tests in the absence of symptoms: 2048

Testing done for patients who were direct contacts of other patients positive for a ITS: 169

In the following section you can find detailed information about tests we have done in key infections, but apart from those which are detailed (syphilis, chlamydia, gonorrhoea and HIV) we have additionally performed some 756 for other pathologies such as:

- Hepatitis B
- Hepatitis C
- Papillomavirus typing
- *Trichomonas*
- *Mycoplasma hominis*
- *Ureaplasma urealyticum*
- *Herpes simplex*
- Anal cytology

We have not provided detailed information about the results of these tests as positive results constitute a very low level of cases for these diseases.

CLINICAL PSYCHOLOGY SESSIONS

92 consultations in clinical psychology have been performed, 80 in Open House Madrid and 12 in Barcelona.

SYPHILIS

Syphilis tests performed: 1208

Cases diagnosed: 76

Latent syphilis: 20
Secondary syphilis: 38
Primary syphilis: 18

Successful treatment outcome: 99.4%

False positives: 2 (0.16%)

Clinical comment: syphilis is still the most common diagnosis between men who have sex with men, but this year we have seen a few more cases in heterosexuals, especially in immigrants. Cases successfully treated in Open House were around 99.4% which is a figure greatly superior to the minimum treatment standards established by the European health authorities.

GONORRHOEA

Gonorrhoea tests performed: 1819

Rapid immunoassay tests: 727

Nucleic acid amplification tests: 1092

Cases diagnosed: 117

Gonorrhoea cervicitis: 2
Pharyngeal gonorrhoea: 9
Gonorrhoea urethritis: 79
Gonorrhoea uroprostatitis: 16
Gonorrhoea reactive arthritis: 1
Gonorrhoea proctitis: 10

Successful treatment outcome: 99,7%

False positives: 4 (0.49%)

Cases of true antibiotic resistance identified: 1

Serious adverse reacciones due to dual antigonococcal therapy: 0

Clinical comments: this year we have seen almost the same number of cases of gonorrhoea as chlamydia, with more pharyngeal (throat) and rectal infections than previous years due to the new highly sensitive nucleic acid amplification tests we have acquired that detect the DNA of these bacteria at a microscopic level.

Treatment of gonorrhoea in Open House consists in the combined use of two antibiotics at the same time in order to prevent the development of resistant strains, but this year we have only seen one case of true drug resistance and the double antibiotic has been well tolerated.

CHLAMYDIA

Chlamydia tests performed: 1729

Rapid immunoassay tests: 617

Nucleic acid amplification tests: 1112

Cases diagnosed: 121

Chlamydia cervicitis: 14
Pharyngeal chlamydia: 3
Chlamydia urethritis: 85
Chlamydia proctitis: 14
Chlamydia proctitis: 5
Reiter's syndrome: 2
Lymphogranuloma venereum: 0

Successful treatment outcome: 99.2%

False positives: 4 (0.23%)

HIV

HIV tests performed: 1496

Antibody testing: 895

Antibody and p24 antigen combined tests: 601

Cases diagnosed: 14

Anal sex between men: 11
Anal sex between heterosexuales: 2
Vaginal sex (women): 1
Vaginal sex (men): 0
Oral sex: 0

False positives: 2 (0.13%)

NON-SPECIFIC URETHRITIS (NSU) & PROSTATITIS (NSP)

NSU cases diagnosed: 192

Successful treatment outcome: 98.2%

NSP cases diagnosed: 64

Successful treatment outcome: 97.1%

Clinical comments: in cases of non-specific urethritis or prostatitis (with no identifiable sexually transmitted pathogen) we continue to have a high success rate in investigation and correct treatment of these two conditions without having to refer cases to a urologist.

GENITAL WARTS

New cases seen: 129

Successful treatment after first session of cryotherapy: 92%

Successful treatment after two sessions of cryotherapy: 96%

Referral for laser or surgical ablation: 4%

ANTIBACTERIAL POST EXPOSURE PROPHYLAXIS

Open House's policy is to reduce the use of prophylactic antibiotics to a minimum since multiple antibiotics should be given at the same time for maximum efficacy. Complying strictly with our protocol inclusion and exclusion criteria we have only administered prophylaxis 19 times this year.

MOLUSCUM CONTAGIOSUM

New cases seen: 27

Successful treatment after first session of cryotherapy: 98%

Successful treatment after two or more sessions of cryotherapy: 99%

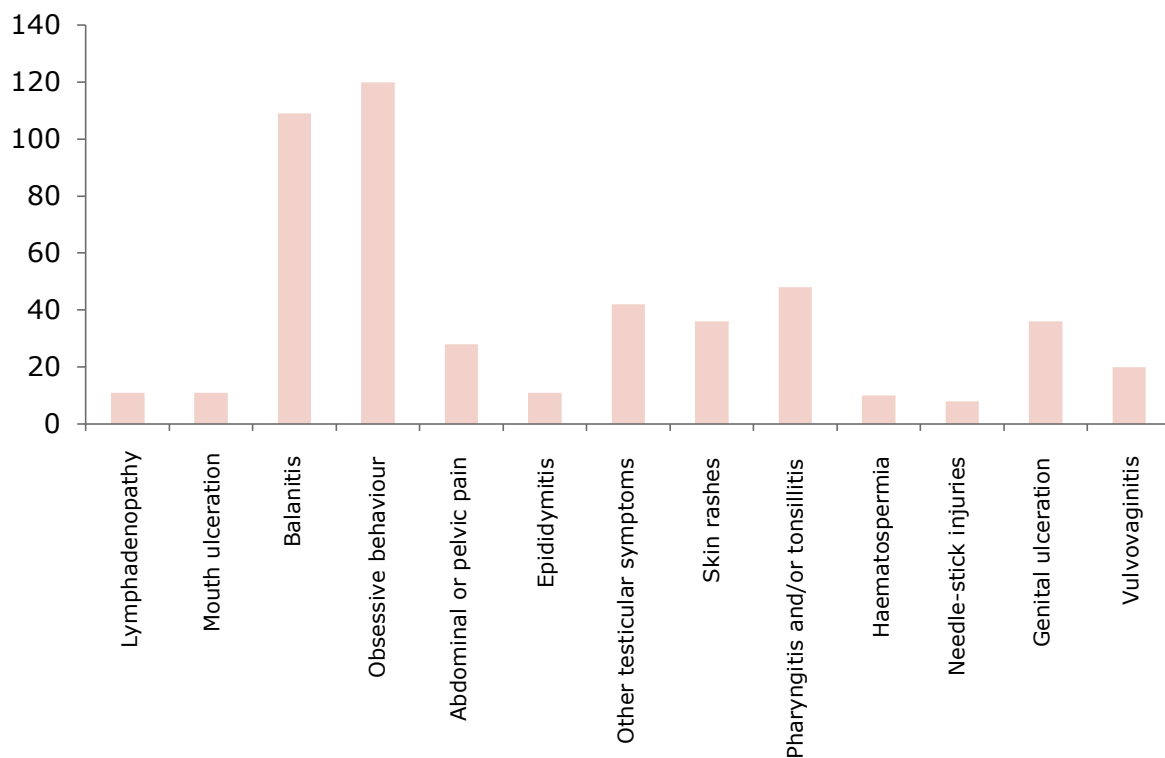
Referral for ablation by a specialist: 1%

CASES OF NOTE

We plan to publish three unusual cases with have seen this year of atypical syphilis presentation in the hands of two patients and a case of arthritis of the knee due to gonorrhoea.

OTHER PATHOLOGY

Graph 7: Number of cases of other diseases and clinical states investigated and managed by Open House in 2014.



RESEARCH

Results from our syphilis study published in the World AIDS Conference of 2013 have allowed us to have more confidence using our rapid test as a diagnostic, and hence being able to initiate treatment earlier. Throughout 2014 we have continued to compare our test results to conventional tests and still see consistently that we have a vastly superior tool. You can read about our publication following this link.

Chapman et al Sex Transm Infect 2013;89:A109-A110

Our far-reaching epidemiological study "CLEMENTE" started its existence at the end of 2014 with the study protocol being finalised. In 2015 we will start this study which will give us a great deal of valuable information about chlamydia in Spain.

CONTACTS & QUERIES

For further information about the contents of this document, please write to our medical director, Dr. Steve Chapman at: **lequipo@openhouse.es**